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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

MAILED

Application Number: 09/873,500

JAN 31 2007

Filing Date: June 04, 2001

GROUP 3600

Appellant(s): WARE ET AL.

C. Andrew Im
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12 October 2006 appealing from the Office action mailed 27 January 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

Art Unit: 3626

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,067,523

Bair et al.

5-2000

Ware et al., "The Search for More Practical and More Precise Outcomes Measures,"

The Quality of Life Newsletter, January - April 1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-6, 8-10, 12-15, 17-23, 25-27, and 29-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ware et al. (Ware, Jr., John E., Jakob Bjorner, and Mark Kosinski, Dynamic Health Assessments: The Search for More Practical and More Precise Outcomes Measures, The Quality of Life Newsletter, January 1999-April 1999),

for substantially the same reasons given in the previous Office Action (mailed 18 October 2005), and further in view of Bair et al. (6,067,523).

(A) As per claim 1, Ware discloses a method for making a dynamic healthcare assessment comprising:

(a) selecting questions for a customized questionnaire or test pertaining to a patient's health status, wherein the health status pertains to health conditions such as mental health issues or headaches, wherein the test has multiple questions (pg. 11, col. 2-3, pg. 12 col. 1-3), wherein the customized test or dynamic assessment is generated based on whether a patient is a headache sufferer (reads on "patient characteristics) (page 12, col. 3);

(b) administering said questionnaire or test to a patient by providing one question at a time to said patient (pg. 12, col. 1); and

(c) after each question, evaluating answers provided by said patient to administered questions to estimate a score and a confidence level in the accuracy of said estimated score and dynamically modifying said test if said estimated confidence level is outside a pre-determined threshold (pg. 11 col. 3 par. 2, pg. 12 col. 1-2, pg. 13 col. 1-2), wherein the test is dynamically modified based on the immediately prior question (see Figure 3, page. 12, col. 1).

As per the recitation of "the threshold varying as a function of the estimated score," Ware discloses the following steps in Figure 3: step 3 and 4) re-estimating the score, step 4) re-estimating the confidence interval, step 5) determining whether a

stopping rule is satisfied and determining whether the score has been estimated within a preset standard of precision based on the confidence interval, wherein once the precision standard is met, the computer either begins assessing the next concept or ends the battery (considered to be a form of "threshold"), wherein the precision standard based on the confidence interval (i.e., the threshold) is set based on each patient's score (see page 12, col. 1-2). Note, Ware's discussion of where the preset standard of precision is +/- 5.4 for the lowest scoring patients, where these patients scored near or below an established cutoff point used in screening patients for psychiatric disorders. Note, that Ware discloses that the standard of precision was relaxed to +/- 7.9 or less for patients at or above the 90th percentile. (See page 12, col. 1 bottom to top of col. 2). It appears from this disclosure that Ware teaches that the threshold (i.e., precision standard based on the confidence interval) varies as a function of the estimated score.

Ware discloses the questionnaire or test pertaining to severity of headaches (pg. 12 col. 3 par. 1), general overall health (pg. 12 col. 3 par. 1), effectiveness of treatment, self-perceived status (pg. 12, col. 1-3 see mental health and headaches discussion, pg. 13 col. 1-2 see mental health discussion). These are forms of "health domains."

Ware does not expressly disclose the health domains being selected by a patient or a health care provider.

Bair discloses administering a questionnaire that is customized to a patient based on the specific treatment plan of each patient, wherein the treatment plan comprises questionnaires selected by a health care provider (i.e., therapist), wherein the questionnaires includes such areas as anxiety disorders, aggressiveness potential,

Art Unit: 3626

and disability evaluation (Fig. 11, 17, col. 2 lines 58-65, col. 11 line 45 to col. 12 line 55). The areas of the questionnaire described above are considered to be a form of "health domain."

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Bair within the method of Ware with the motivation of providing tests or a series of tests at specified time intervals in order to monitor a patient's progress (Bair; col. 2 lines 5-10).

(B) As per claim 2, Ware discloses generating a report for a physician and patient, wherein the report can be used to develop an effective treatment plan and then monitor how much the patient is helped (pg. 12 col. 3 par. 2).

(C) As per claim 3, Ware discloses the questionnaire pertaining to mental health assessments or headache sufferers, wherein the questions focus on the severity of a patient's headache and disability as well as how the headache's affect individual patient's in terms of their work productivity, social function, and family relationships (pg. 12 col. 3 par. 1-2).

(D) As per claims 4-5, Ware discloses ranking the plurality of questions in accordance with said estimated score and selecting a question based on the ranking, where the question has not been administered to the patient and the selecting a question includes selecting the highest ranked question (see pg. 12 col. 1). Note Ware's discussion of

Art Unit: 3626

beginning with an initial score estimate, then selecting and presenting the optimal scale item based on the initial score estimate, then scoring the optimal scale item and re-estimating the health score and confidence interval.

(E) As per claim 6, Ware discloses terminating said administration of said test if it is determined that said estimated confidence level is within said threshold (pg. 12 col. 1 par. 2-3).

(F) As per claim 7, Ware discloses the threshold varying as a function of the estimated score (pg. 12 col. 1-2).

(G) As per claim 9, Ware discloses choosing an answer to a question on the bipolar general mental health of a patient, where the answers range from emotional distress to well being, including extremely bothered and not at all bothered (pg. 13 col. 1-2) (it is noted the answers cited by Ware are considered to be a form of a "list of possible answers").

(H) As per claims 10-11, Ware discloses estimating each person's score and confidence level based on their answers including analyzing the answers for systematic errors and quality (pg. 13 col. 1-2).

(I) As per claim 13, Ware discloses comparing said answers provided by said patient with answers provided by other patients in said mental health questionnaires (pg. 12 col. 1-2 comparing scores to 2,753 patients who participated in the study, pg. 13 col. 1-2).

(J) As per claims 14-16, Ware discloses administering the dynamic assessment over a web browser and Internet or telephone (pg. 12 col. 3 par. 1-2).

(K) As per claim 15, Ware discloses the report being received over the Internet or telephone (pg. 12 col. 3 par. 1-2).

(L) As per claim 17, Ware discloses the questionnaire or test pertaining to severity of headaches (pg. 12 col. 3 par. 1), general overall health (pg. 12 col. 3 par. 1), effectiveness of treatment, self-perceived status (pg. 12, col. 1-3 see mental health and headaches discussion, pg. 13 col. 1-2 see mental health discussion).

(M) System claims 18-24, 26-28, and 31-34 repeat the subject matter of method claims 1-7, 9-11, and 14-17, respectively, as a set of apparatus elements rather than as a series of steps. As the underlying processes of claims 1-7, 9-11, and 14-17 have been shown to be fully disclosed by the teachings of Ware in the above rejections of claims 1-7, 9-11, and 14-17, it is readily apparent that the system disclosed collectively by Ware includes the apparatus to perform these functions. Note, the discussion in Ware of a

Art Unit: 3626

computerized adaptive test and software designed to implement the method discussed in claim 1 (pg. 11 col. 2-3). As such, these limitations are rejected for the same reasons given above for method claims 1-7, 9-11, and 14-17, and incorporated herein.

(N) Claims 35-40 repeat method and system claims 1, 6, 17, and 18, and are therefore rejected for the same reasons as those claims.

(O) As per claim 41, Bair discloses administering a questionnaire that is customized to a patient based on the specific treatment plan of each patient, wherein the treatment plan comprises one or more questionnaires selected by a health care provider (i.e., therapist), wherein the questionnaires includes such areas as anxiety disorders, aggressiveness potential, and disability evaluation (Fig. 11, 17, col. 2 lines 58-65, col. 11 line 45 to col. 12 line 55). The areas of the questionnaire described above are considered to be a form of "at least two health domains."

(P) As per claims 42-45, Bair discloses:

- (a) administering the test before a variable is introduced, wherein said variable includes a pharmaceutical such as Zoloft or Xanax, interventions or therapies (Fig. 1, 29-31, 27B, col. 12 lines 5-55, col. 14 line 43 to col. 15 line 14);
- (b) readministering the questionnaire after the variable is introduced (Fig. 1, 16, 29-31, 27B, col. 6 lines 11-21, col. 12 lines 5-55, col. 14 line 43 to col. 15 line 14, col. 15 lines 15-51); and

(c) comparing resultant data obtained from each separate administration of said test, wherein said resultant data is indicative of efficacy (see "patient satisfaction and assessing treatment in order to gauge the effect of the treatment upon the behavioral problem) or impact of the introduction of said variable on said health status or health care of said patient (Abstract; Fig. 29-31, 27B, col. 12 lines 5-55, col. 14 line 43 to col. 15 line 14, col. 15 lines 15-51).

The motivation for including the features of Bair within the method and system of Ware being to assess treatment and patient satisfaction (Bair; col. 15 lines 20-30).

(10) Response to Argument

(1) At pages 4-6 of Appellant's Brief, Appellant argues that the combined references fail to teach or suggest all of the claim limitations. In particular, Appellant argues that Ware and Bair do not teach or suggest a threshold which varies as a function of the estimated score during the administration of a test as recited in claims 1, 18, 35, and 39.

In response, it is respectfully submitted that claim 1 recites the following:

- after each question, evaluating answers provided by said patient to administered questions to estimate a score and a confidence level in the accuracy of said estimated score (Figure 3, page 12: col. 1 and 2); and
- dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside a threshold (Figure 3, page 12: col. 1 and 2) (see estimate health score and confidence interval, is

- stopping rule satisfied?, select and present optimal scale item or the most informative item); and
- wherein said threshold varies as a function of said estimated score (the precision standard varies as a function of the score) (Figure 3, page 12: col. 1 and 2, page 13). It is noted that in Ware in col. 2 discusses that the precision standard can be changed or relaxed depending on the scores for a patient.

The Examiner respectfully submits that Ware teaches a threshold varying as a function of an estimated score. Appellant argues that Appellant's invention teaches a method of assessing the health status or health care of a patient wherein the threshold varies as a function of the estimated score within or during a single test. However, Appellant's invention does not claim this feature. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim 1 simply requires that a threshold vary as a function of said estimated score. This "wherein" clause is not an active step in the method and is not related to the "dynamically modifying" step. Thus, the Examiner has provided prior art that discloses "wherein the threshold varies as a function of said estimated score." This is based on the broadest reasonable interpretation of Ware. It is also noted that the Ware reference is some of the Appellant's own work.

(2) At pages 6-7 of Appellant's Brief, Appellant argues that there is no motivation to combine the prior art.

In response to Appellant's argument that there is no motivation to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner has provided a motivation directly from the references themselves.

Applicant argues that Ware and Blair are not "even remotely concerned with the problem of providing flexibility in the administration of the test by mimicking the evaluation process performed by a professional health care provider." However, on page 11, col. 2 of Ware, Ware discusses matching questions to the respondent's level of health. Ware discusses "This strategy has been used to achieve short and precise educational and psychological tests for decades. They are called "computerized adaptive tests." The result is a simple form of artificial intelligence that selects questions tailored to the test-taker, shortens or lengthens the test to achieve the desired precision, scores everyone on a standard metric so that results can be compared, and displays results instantly." Further on page 11, col. 3, Ware discusses how QualityMetric has developed new software with the specific features necessary for the next generation of health assessments, which will be administered dynamically." On page 12, col. 3, Ware discusses that *dynamic health assessments* can be administered at the point of care or in a patient's home and can be used to develop an effective

Art Unit: 3626

treatment plan and can be used to monitor how much the patient is helped. It appears from these discussions that Ware is "concerned with the problem of providing flexibility in the administration of the test by mimicking the evaluation process performed by a professional health care provider."

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



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January 24, 2007

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